

AMENDMENTS TO THE CLAIMS

Please amend the Claims as follows:

1. (Currently Amended) A rotary blood pump for use in a heart assist device, the pump comprising:

an impeller an even number of blades and generally circumferentially extending struts interconnecting the blades at an outer periphery of the impeller; and

a pump housing wherein the impeller is suspended in use within the pump housing exclusively by hydrodynamic thrust forces generated by relative movement of the impeller with respect to and within the pump housing; and wherein at least one of the impeller and the pump housing includes at least a first deformed surface lying on at least part of a first face and a second deformed surface lying on at least a part of a second face which, in use, move relative to respective facing surfaces on the other of the at least one of the impeller and the pump housing thereby to form at least two relatively moving surface pairs which generate relative hydrodynamic thrust between the impeller and the pump housing which includes everywhere a localized thrust component substantially and everywhere normal to the plane of movement of the first deformed surface and the second deformed surface with respect to the facing surfaces; and wherein the combined effect of the localized normal forces generated on the surfaces of the impeller is to produce resistive forces against movement in three translational and two rotational degrees of freedom.

2. (Previously Presented) The blood pump of Claim 1 wherein the first deformed surface lies on at least part of a first face of the impeller.

3. (Previously Presented) The blood pump of Claim 1 wherein the second deformed surface lies on a second face of the impeller.

4. (Previously Presented) The blood pump of Claim 1 wherein the first deformed surface lies on a first inner face of the housing.

5. (Previously Presented) The blood pump of Claim 1 wherein the second deformed surface lies on a second inner face of the housing.

6. (Previously Presented) The blood pump of Claim 2 wherein the first deformed surface covers entirely the first face.

7. (Previously Presented) The blood pump of Claim 2 wherein the first deformed surface covers entirely the second face.

8. (Previously Presented) The blood pump of Claim 1 wherein the first face lies at an acute angle relative to the second face.

9. (Previously Presented) The blood pump of Claim 1 wherein the hydrodynamic forces are augmented by at least one secondary force to support the impeller for rotation within the housing.

10. (Previously Presented) The blood pump of Claim 9 wherein the at least one secondary force comprises magnetic force.

11. (Previously Presented) The blood pump of Claim 1 wherein the first deformed surface comprises deformations in the first face of the impeller whereby a gap between the first deformed surface and a first facing surface on the housing forms, in use, a restriction in the form of a reducing distance between the surfaces with respect to the relative line of movement of the first deformed surface.

12. (Previously Presented) The blood pump of Claim 11 wherein the gap takes the form of a wedge shaped restriction which generates a thrust in use.

13. (Previously Presented) The blood pump of Claim 1 wherein the pump is of centrifugal type or mixed flow type with impeller blades open on both front and back faces of the pump housing.

14. (Previously Presented) The blood pump of Claim 1 wherein the front face of the pump housing is made conical, in order that the thrust perpendicular to a conical surface of the impeller has a radial component, which provides a radial restoring force to a radial displacement of the impeller axis during use.

15. (Previously Presented) The blood pump of Claim 1 wherein the driving torque of the impeller derives from magnetic interaction between permanent magnets within blades of the impeller and oscillating currents in windings encapsulated in the pump housing.

16. (Previously Presented) The pump of Claim 15 wherein the blades include magnetic material therein, the magnetic material being encapsulated within a biocompatible shell or coating.

17. (Previously Presented) The pump of Claim 16 wherein the biocompatible shell or coating comprises a coating which can be applied at low temperature.

18. (Previously Presented) The pump of Claim 16 wherein internal walls of the pump which can come into contact with the blades during use are coated with a hard material.

19. (Previously Presented) The pump of Claim 1 wherein the impeller comprises an upper conical shroud having a deformed surface thereon and wherein blades of the impeller are supported below the shroud.

20. (Previously Presented) The pump of Claim 19 wherein the impeller further includes a lower shroud mounted in opposed relationship to the upper conical shroud and wherein the blades are supported within the upper conical shroud and the lower shroud.

21. (Previously Presented) The pump of Claim 1 wherein at least one of the deformed surfaces is located on the impeller.

22. (Previously Presented) The pump of Claim 1 wherein at least one of the deformed surfaces are located on the housing.

23. (Previously Presented) The pump of Claim 1 wherein the combined effect of the localized normal forces generated on the surfaces of the impeller is to produce resistive forces against movement so as to support the impeller for rotational movement within the housing by the hydrodynamic thrust forces in an adaptive manner whereby the impeller is repositioned, in use, so as to conserve energy as a function of fluid viscosity.

24. (Previously Presented) The pump of Claim 1 wherein the combined effect of the localized normal forces is to produce resistive forces against movement in three translational and two rotational degrees of freedom so as to support the impeller for rotational movement within the housing by the hydrodynamic thrust forces.

25. (Previously Presented) The pump of Claim 1 wherein forces imposed on the impeller in use are controlled by design so that, over a predetermined range of operating parameters, the hydrodynamic thrust forces provide sufficient thrust to maintain the impeller suspended in use within the pump housing.

26. (Previously Presented) The pump of Claim 1 further comprising an electrical drive which urges the impeller to rotate with respect to the pump housing and a controller

sensing the speed and input power from electrical parameters of the electrical drive to estimate, in use, head pressure and/or flow rate of the pump.

27. (Previously Presented) The pump of Claim 25 further comprising a regulator in communication with the controller and the electrical drive so as to sense and inhibit under pumping and regurgitation.

28. (Currently Amended) An estimation and control system for a pump, the pump of the type having an impeller located within a pump cavity in a pump housing, the housing having a fluid inlet in fluid communication with the cavity, the housing having a fluid outlet in fluid communication with the pump cavity, the impeller urged to rotate about an impeller axis so as to cause fluid to be urged from the inlet through the pump cavity to the pump outlet, the impeller urged to rotate by a drive, the impeller supported for rotational movement by an impeller support, the impeller maintained at or near a predetermined speed of rotation by a controller acting on the drive, the controller receiving as input variables a first input variable comprising power consumed by the drive, the controller receiving a second input variable comprising actual speed of rotation of the impeller; the controller thereby estimating at least one of head across the pump and rate of flow of the fluid to an approximation of predetermined accuracy relying on signals available from the drive ,wherein the control system is adapted to maintain the speed of rotation of the impeller within a range whereby the impeller, in use, substantially resists five degrees of freedom of movement with respect to the pump housing solely via hydrodynamic forces and predominantly without any external intervention from the control system to control the position of the impeller with respect to the housing.

29. (Previously Presented) The system of Claim 28 wherein the pump has a substantially constant steady state head versus flow rate characteristic over a predetermined flow rate range.

30. (Previously Presented) The system of Claim 28 wherein blades of the impeller are such that a midline chord angle of the blades is inclined substantially radially to internal walls of the pump cavity.

31. (Previously Presented) The system of Claim 28 which relies on sensing of EMF induced in one or more coils forming part of the drive.

Appl. No. : **09/980,682**
Filed : **August 15, 2002**

32. (Previously Presented) The system of Claim 28 wherein the impeller includes blades inclined such that relative velocity of fluid off-flow from the blades is substantially radial with respect to the impeller axis.

33. (Cancelled)

34. (Previously Presented) The system of Claim 28 wherein the pump is a low specific speed pump.

35. (Previously Presented) The system of Claim 34 wherein the pump has a specific speed in the range $100\text{-}2000 \text{ rev/min}(\text{gal/min})^{1/2}\text{ft}^{-3/4}$.

36. (Previously Presented) The system of Claim 34 wherein the pump has a specific speed of approximately $900\text{-}1000 \text{ rev/min}(\text{gal/min})^{1/2}\text{ft}^{-3/4}$.

37. (Currently Amended) The system of Claim 28, ~~further comprising~~ wherein the pump comprises a rotary blood pump and wherein the ~~pump has an~~ impeller is suspended hydrodynamically within a pump housing by thrust forces generated by the impeller during movement in use of the impeller as it rotates about an impeller axis.

38. (Previously Presented) The blood pump and estimation and control system of Claim 37 wherein the thrust forces are generated by blades of the impeller.

39. (Previously Presented) The blood pump and estimation and control system of Claim 38 wherein the thrust forces are generated by forces of the blades of the impeller.

40. (Previously Presented) The blood pump and estimation and control system of Claim 39 wherein the blades are tapered or non-planar, so that a thrust is created between the edges and the pump housing during relative movement therebetween.

41. (Previously Presented) The blood pump and estimation and control system of Claim 38 wherein the blades are shaped such that the gap at the leading edge of the blade is greater than at the trailing edge and thus the fluid which is drawn through the gap experiences a wedge shaped restriction which generates a thrust.

42. (Previously Presented) The blood pump and estimation and control system of Claim 37 wherein the pump is of centrifugal type or mixed flow type with blades of the impeller open on both front and back faces of the pump housing.

43. (Previously Presented) The blood pump and estimation and control system of Claim 42 wherein the front face of the pump housing is made conical, in order that the thrust

force perpendicular to the conical surface has a radial component, which provides a radial restoring force to a radial displacement of the impeller axis during use.

44. (Previously Presented) The blood pump and estimation and control system of Claim 38 wherein the driving torque of the impeller derives from the magnetic interaction between permanent magnets within the blades of the impeller and oscillating currents in windings encapsulated in the pump housing.

45. (Previously Presented) The rotary blood pump and estimation and control system of Claim 37 wherein the pump is of axial type.

46. (Previously Presented) The rotary blood pump and estimation and control system of Claim 45 wherein, within a uniform cylindrical section of the pump housing, the impeller includes tapered blade bearing surfaces which form a radial hydrodynamic bearing.

47. (Previously Presented) The rotary blood pump and estimation and control system of Claim 46 wherein an interior of the pump housing is made with reducing radius at the two ends, and wherein the end hydrodynamic thrust forces have an axial component which can provide the axial bearing.

48. (Previously Presented) The rotary blood pump and estimation and control system of Claim 46 wherein magnetic forces provide the axial bearing.

49. (Currently Amended) The rotary blood pump and estimation and control system of Claim 37, further comprising a housing within which ~~an~~ the impeller acts by rotation about an impeller axis to cause a pressure differential between an inlet side of the pump housing of the pump and an outlet side of the pump housing of the pump, wherein the impeller is suspended hydrodynamically by thrust forces generated by the impeller during movement in use of the impeller

50. (Previously Presented) The rotary blood pump and estimation and control system of Claim 49 wherein the impeller includes magnetic material therein, the magnetic material encapsulated within a biocompatible shell or coating.

51. (Previously Presented) The rotary blood pump and estimation and control system of Claim 50 wherein the biocompatible shell or coating comprises of a material which can be applied at low temperature.

52. (Currently Amended) The rotary blood pump and estimation and control system of Claim 49 wherein internal walls of the pump which can come into contact with the blades of the impeller during use are coated with a hard material.

53. (Currently Amended) The rotary blood pump and estimation and control system of Claim 37, wherein the pump is a seal-less and shaft-less pump and ~~comprises a~~ wherein the housing defining defines a chamber therein and ~~having~~ has a liquid inlet to the chamber and a liquid outlet from the chamber; the ~~pump further including an~~ impeller being located within the chamber; the arrangement between the impeller, the inlet, the outlet and the internal walls of the chamber being such that upon rotation of the impeller about an impeller axis relative to the housing, liquid is urged from the inlet through the chamber to the outlet; and wherein thrust forces are generated by relative movement of the impeller with respect to the housing

54. (Previously Presented) The pump of Claim 53 wherein the thrust forces are generated by blades of the impeller.

55. (Previously Presented) The pump of Claim 54 wherein the thrust forces are generated by surfaces of the blades of the impeller.

56. (Previously Presented) The pump of Claim 55 wherein the surfaces of the blades are tapered or non-planar.

57. (Previously Presented) The pump of Claim 53 wherein the surfaces of the blades are shaped such that a gap at the leading edge of each of the blades is greater than at a trailing edge thereof whereby fluid which is drawn through the gap experiences a wedge shaped restriction which generates a thrust relative to the housing.

58. (Previously Presented) The pump of Claim 54 wherein the pump is of centrifugal type or mixed flow type with the blades of the impeller open on both front and back faces of the pump housing.

59. (Previously Presented) The pump of Claim 58 wherein the front face of the pump housing is made conical, in order that the thrust perpendicular to its conical surface at any point has a radial component, which provides a radial restoring force to a radial displacement of the impeller axis.

60. (Currently Amended) The pump of Claim 58 wherein the driving torque of the impeller derives from the magnetic interaction between permanent magnets within the blades of the impeller and oscillating currents in windings encapsulated in the pump housing.

61. (Previously Presented) The pump of Claim 53 wherein the pump is of axial type.

62. (Previously Presented) The pump of Claim 61 wherein, within a uniform cylindrical section of the pump housing, tapered blade surfaces form a radial hydrodynamic bearing.

63. (Previously Presented) The pump of Claim 61 wherein the pump housing is made with reducing radius at opposed ends, and wherein the end hydrodynamic thrust forces have an axial component which can provide the axial bearing.

64. (Previously Presented) The pump of Claim 61 wherein magnetic forces provide the axial bearing.

65. (Previously Amended) The rotary blood pump and estimation and control system of Claim 49, wherein the impeller is suspended hydrodynamically in at least one of a radial or axial direction by thrust forces generated by the impeller during movement in use of the impeller.

66. (Previously Presented) The pump of Claim 65 wherein the impeller includes magnetic material therein, the magnetic material encapsulated within a biocompatible shell or coating.

67. (Previously Presented) The pump of Claim 66 wherein the biocompatible shell or coating comprises a diamond coating.

68. (Previously Presented) The pump of Claim 66 wherein internal walls of the pump which can come into contact with the impeller during use are coated with a hard material.

69. (Previously Presented) The pump of Claim 65 wherein at least upper and lower surfaces of blades of the impeller are interconnected by a structure having deformities in the outer surfaces thereof so that a thrust is created between the surfaces and the adjacent pump casing during relative movement therebetween.

70. (Withdrawn) A method of hydrodynamically suspending and controlling an impeller within a rotary pump for support in at least one of a radial and axial direction; the method comprising:

incorporating a deformed surface in at least part of the impeller so that, in use, a thrust is created between the deformed surface and an adjacent pump housing during relative movement therebetween; and

maintaining the speed of rotation of the impeller within a range whereby the impeller, in use, substantially resists five degrees of freedom of movement with respect to the pump housing without any external intervention.

71. (Withdrawn) The method of Claim 70 wherein the deformed surface includes a taper.

72. (Withdrawn) The method of Claim 71 wherein the taper is arranged so that there is a larger gap at a leading edge thereof between the impeller and the pump housing than at a trailing edge thereof.

73. (Currently Amended) An estimation and control system for a pump; the pump of the type having an impeller located within a pump cavity in a pump housing; the housing having a fluid inlet in fluid communication with the cavity; the housing having a fluid outlet in fluid communication with the pump cavity; the impeller urged to rotate about an impeller axis so as to cause fluid to be urged from the inlet through the pump cavity to the pump outlet; the impeller urged to rotate by an impeller drive; impeller supported for rotational movement by an impeller support; the pump maintained at or near a predetermined operating point by a controller acting on the impeller drive; the controller receiving as input variables at least a first input variable derived from the impeller drive; the controller receiving at least a second input variable also derived from the impeller drive; the controller thereby calculating an estimate of the operating point to an approximation of predetermined accuracy relying on signals available from the impeller drive; the controller controlling the pump by comparing the predetermined operating point with the estimate of the operating point; and wherein instantaneous pump speed and electrical input power are allowed to be modulated by a heart, in use, by appropriate selection of a control time constant to reduce over and under pumping.

74. (Previously Presented) The system of Claim 73 in combination with the pump.

75. (Previously Presented) The system of Claim 73 wherein the control time constant of the control system is greater than the rotational, inertial time constant of the impeller.

76. (Previously Presented) The system of Claim 73 wherein the control time constant is at least one cardiac cycle.

77. (Previously Presented) The system of Claim 73 wherein the first input variable comprises instantaneous pump speed.

78. (Previously Presented) The system of Claim 73 wherein the second input variable is representative of electrical input power to the impeller drive.

79. (Currently Amended) The system of Claim 73 wherein the pump is arranged to operate according to a relatively flat HQ pressure versus flow rate characteristic.

80. (Previously Presented) The system of Claim 73 wherein variation in speed of the impeller, in use, is permitted and then utilized to calculate an improved estimate of pressure rise across the pump and flow through it.

81. (Currently Amended) The system of Claim 79 wherein the HQ pressure versus flow rate characteristic is sufficiently flat that ~~head~~ the pressure will remain constant to a sufficient approximation over a predetermined operating range whereby, over the operating range, the system can assume that pump speed will be proportional to flow rate.

82. (Previously Presented) The system of Claim 63 wherein the predetermined operating point is calculated so as to maintain minimum pump speed such that the minimum head pressure across the pump does not increase.

83. (Previously Presented) The system of Claim 82 wherein the system ensures that minimum pump speed is always at least the minimum speed at which non-regurgitant flow will occur.

84. (Previously Presented) The system of Claim 83 wherein the speed at which regurgitant or negative flow will begin to occur is determined as that pump set point speed where levels and phase lags between pump outlet and inlet pressures fall during diastole cause flow reversal.

85. (Previously Presented) The system of Claim 84 wherein the pump speed at which regurgitation is calculated to occur is calculated according to:

$$N_{\text{regurg}} = N(t) \text{ for } Q_{\text{diastole}} = OL/\text{min}$$

86. (Previously Presented) A physiological controller for use in association with a pump; the controller monitoring estimated flow of fluid within the pump and pressure across the pump by non-contact means thereby to control speed of rotation of an impeller within the pump; and wherein the controller permits impeller speed to vary under a pulsating fluid load thereby to assist in calculation and adjustment of impeller speed set point.

87. (Previously Presented) The controller of Claim 86 wherein the fluid is blood; the controller including a processor which determines optimal pump output for the pump to meet demand for blood at all physiological states of a mammal in which the pump is installed.

88. (Previously Presented) The controller of Claim 87 wherein the processor includes as a control aim to adjust pump output so as to eliminate suction collapse of blood vessels.

89. (Previously Presented) The controller of Claim 88 wherein the processor calculates flow and head to discern optimal pumping based on collapse and overpumping.

90. (Previously Presented) The controller of Claim 88 wherein the processor calculates values of speed and power (peak and RMS values) to discern optimal pumping based on collapse and overpumping.

91. (Previously Presented) The controller of Claim 88 wherein the processor includes a control aim which adjusts optimal pump output to a point close to where the aortic valve just opens or just fails to open.

92. (Previously Presented) The controller of Claim 91 wherein the pump comprises a ventricular assist device adapted to assist operation of a ventricle of a heart and wherein the processor adjusts pump output so that, in alternating fashion, the ventricle in conjunction with the aortic valve is allowed to eject blood over a predetermined number of cardiac cycles and then the ventricle in conjunction with the aortic valve is caused to not eject blood over a following predetermined number of cardiac cycles.

93. (Withdrawn) An estimation and control system for a pump; the pump of the type having an impeller located within a pump cavity in a pump housing; the housing having a

fluid inlet in fluid communication with the cavity; the housing having a fluid outlet in fluid communication with the pump cavity; the impeller urged to rotate about an impeller axis so as to cause fluid to be urged from the inlet through the pump cavity to the pump outlet; the impeller urged to rotate by an impeller drive; the impeller supported for rotational movement by an impeller support; the pump maintained at or near a predetermined operating point by a controller acting on the impeller drive; the controller receiving as input variables at least a first input variable derived from the impeller drive; the controller receiving at least a second input variable also derived from the impeller drive; the controller thereby calculating an estimate of the operating point to an approximation of predetermined accuracy relying on signals available from the impeller drive; the controller controlling the pump by comparing the predetermined operating point with the estimate of the operating point; and wherein the pump is arranged to operate according to a relatively flat HQ characteristic.

94. (Withdrawn) The estimation and control system of Claim 93 wherein there is no inflexion point in the HQ characteristic at or near the predetermined operating point.

95. (Withdrawn) The estimation and control system of Claim 93 wherein the pump includes near-radial off-flow from the impeller.

96. (Withdrawn) The estimation and control system of Claim 93 wherein the pump has a low specific speed.